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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/560,744

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Tadashi Kokubo

TAN-357

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7590

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EXAMINER

HOLT, ANDRIAE M

ART UNIT

PAPER NUMBER

1616

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/560,744	Applicant(s) KOKUBO ET AL.	
	Examiner Andriae M. Holt	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to Applicant's amendment filed November 17, 2009. Claims 1-16 are pending in the application. Claims 1, 3-5, and 7-16 have been amended. Claims 1-16 will presently be examined to the extent they read on the elected subject matter of record.

Status of the Claims

The rejection of claims 1-16 under 35 U.S.C. 103 (a) as being unpatentable over JP 2002-248163 **is maintained**.

The rejection of claims 1-16 under 35 U.S.C. 103 (a) as being unpatentable over Kokubo (WO 02/089864) in view of Fujita et al. (US 4,190,689) U.S. Patent Application Publication 2004/0126406 used as a translation **is maintained**.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-16 are rejected under 35 U.S.C. 103 (a) as being unpatentable over JP 2002-248163.

Applicant's Invention

Applicant claims a titanium oxide-organic polymer composite material for artificial bone obtained by forming titania gel on the surface of a base material by titania solution treatment by dipping into a solution said base material composed of a polymer compound selected from the group consisting of polyester and nylon. Applicant claims the titania solution is obtained by adding a solution consisting of acidic alcohol and water into alcohol solution of titaniumtetraalkoxide and modifying a titanium oxide membrane which forms apatite having similar Ca/P atom ratio to an apatite of mammalian's bone in supersaturated aqueous solution or from mammalian body fluid by dipping said base material on the surface of which titania gel is formed into hot water.

Determination of the scope of the content of the prior art (MPEP 2141.01)

JP 2002-248163 teaches a composition in which apatite is formed on the surface of a composition containing titanium gel polymer where the polymer is nylon-6, polyethylene or polyethylene terephthalate (paragraphs 0023-0024).

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

JP 2002-248163 does not specifically teach the use of titanium tetraalkoxide as the titanium component.

**Finding of prima facie obviousness
Rationale and Motivation (MPEP 2142-2143)**

It would have been obvious to one of ordinary skill in the art at the time of invention to use the teachings of JP 2002-248163 and use titanium tetraalkoxide as the titanium component as the claims as written are product-by-process claims. The product produced, a titanium oxide-organic polymer composite material for artificial bone is the same. Applicant has not shown how the products are materially different. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)

Therefore, the claimed invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made because every element of the invention has been fairly suggested by the cited references.

Response to Arguments

Applicant's arguments filed November 17, 2009 have been fully considered but they are not persuasive. Applicant argues that JP '163 teaches the titanium source is an ammonium hexafluoro titanate and that the toxicity is unacceptable for in vivo use as an

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artificial bone material. Applicant also argues that the product is defined by the process steps which recite use of titaniumtetraalkoxide and that the claimed product does not contain fluorine and thus necessarily different in composition from the product of JP '163. In response to applicant's arguments, Applicant has argued toxicity, however, the evidence that Applicant supplied, the Petersson Publication, seems to teach the contrary. Petersson et al. teach that the results of the study show that the electric properties of the oxide film are changed both by physical surface treatment (blasting) and chemical treatment (HF etching). Petersson et al. teach that in the chemical treatment, fluoride ions are incorporated in the surface of TiO_2 . This results in lower surface stoichiometry and a higher number of charge carriers compared with the same surface without HF etching. Petersson et al. further teach the beneficial effects of HF treated surface, reported on in the literature, can possibly be explained by the combined effect of increased conductivity and lower surface charge of the oxide due to incorporation of fluoride ions (page 4477-4478, Conclusions). Petersson et al. teach in the relevance to dental implants section, page 4477, 3.5, that the results from the present study also provides an explanation as to the fate of fluoride ions when the implants are introduced into bone. At the implant installation there is likely a pH decrease due to inflammation in the surrounding tissue compared to the normal value in the body. At low pH values, the fluoride ions are adsorbed at the oxide surface by a Columbic force, i.e., an electrostatic force due to the positively charged surface complexes. Petersson et al. teach that since the implants are rinsed in water during the manufacturing process, the excess fluoride ions are probably already released from the

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surface. Depending on how the remaining fluoride ions are bound to the surface, no further release of fluoride ions are likely to take place during the pH increase following the healing process, see col. 2, paragraph 5. Therefore, Petersson et al. teach that there is no risk of toxicity due to fluoride ions.

In response to Applicant's argument that the products are materially different, Applicant has not shown how the products are materially different. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). As stated during the interview, a fluoride ion trapping agent was used in the composition to trap the fluoride ion, thus making the composition non-toxic and that the end product was a titanium oxide layer, one not structurally different from Applicant's invention. For the foregoing reasons, applicants arguments are not found persuasive. The claims remain rejected.

Claims 1-16 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Kokubo (WO 02/089864) in view of Fujita et al. (US 4,190,689) U.S. Patent Application Publication 2004/0126406 used as a translation.

Applicant's Invention

Applicant claims a titanium oxide-organic polymer composite material for artificial bone obtained by forming titania gel on the surface of a base material by titania solution treatment by dipping into a solution said base material composed of a polymer compound selected from the group consisting of polyester and nylon. Applicant claims the titania solution is obtained by adding a solution consisting of acidic alcohol and water into alcohol solution of titaniumtetraalkoxide and modifying a titanium oxide membrane which forms apatite having similar Ca/P atom ratio to an apatite of mammalian's bone in supersaturated aqueous solution or from mammalian body fluid by dipping said base material on the surface of which titania gel is formed into hot water.

***Determination of the scope of the content of the prior art
(MPEP 2141.01)***

Kokubo et al. teach titanium dioxide/organic polymer hybrid materials for artificial bone produced by forming titania gel on the surface of a substrate made of an organic polymer and treating the titania gel with hot water or an aqueous solution of an acid to convert the titania gel into a titanium dioxide membrane on which apatite having such a Ca/P atomic ratio as to constitutes the bone of an mammal can be formed from the body fluid (Abstract). Kokubo et al. further teach that the titanium oxide-organic polymer hybrid material for an artificial bone, wherein the treating of said titania gel with hot water or aqueous solution of acid is carried out by the acid concentration of pH7 or less that forms titania membrane possessing Ti--OH group in anatase fine crystal and/or 1 hour to 1 month period and/or 30° C to 120° C temperature (page 3, paragraph 23).

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Kokubo et al. teach as for the material used to form a substrate, any organic polymer which has affinity to mammal such as human and can form a titania layer which has apatite forming ability in supersaturated aqueous solution with respect to the apatite can be used. Kokubo et al. further teach that polyolefin, e.g. polyethylene or polypropylene, can be a material for substrate composing a titanium oxide-organic polymer hybrid material of the present invention by using an organic group having affinity to polymer and a denature treating agent which forms Si--OH group (page 5, paragraph 52).

Kokubo et al. teach titaniumalkoxide (titaniumalkoxide), tetraethyltitanete (TEOT), or tetraisopropyltitanate (TiPT) (tetraisopropyltitanate) are desirable examples for the titanium source (page 5, paragraph 71). Kokubo et al. teach the process as instantly claimed in paragraphs 57-50 (page 5). The mixture of super D.I. water (water), HNO_3 (acidic alcohol) and $\text{C}_2\text{H}_5\text{OH}$ (ethanol) anhydride is dropped slowly into the mixture of $\text{Ti}(\text{Oi-C}_3\text{H}_7)_4$ and $\text{C}_2\text{H}_5\text{OH}$ anhydride at 5°C and mixed so as to prepare titania solution of mole ratio of 1.0:0.1:0.1:9.25. The obtained IPTS treated EVOH substrate is dipped into said titania solution for 24 hours at the room temperature, picked up by 20 mm/minute rate, then dried at 100°C for 10 minutes.

**Ascertainment of the difference between the prior art and the claims
(MPEP 2141.02)**

Kokubo et al. do not provide any working examples wherein polyolefin, polyester and nylon are the base the material. It is for this reason Fujita et al. is joined as a secondary reference.

Fujita et al. teach a polymeric-shaped article for use as film such as microfilm, overhead projector film, reprographic film, layout base, etc., and for insulating capacitors, which has excellent transparent, slippery and dielectric properties, and the process for realizing the same. Fujita et al. teach the polymeric-shaped article having a polar surface such as polyester, polyamide, polyolefins, polyimide, polyvinyl alcohol, polyethylene terephthalate or polyethylene-2,6-naphthalate, to which is bonded a multiplicity of nodules of TiO_2 . Fujita et al. teach the process being that of exposing at least one side of the surface of the article to water vapor and bringing a tetrafunctional titanium compound such as TiCl_4 , tetraethyltitanate, tetraisopropyltitanate (tetraisopropyltitanate), tetra-n-butyltitanate or mixture thereof, into contact with the surface, the processing temperature being at least greater than 30°C (Abstract). Fujita et al. teach the polymers are preferably in the form of film and include, but are not limited to, polyesters such as polyethylene terephthalate and polyethylene-2, 6-naphthalate; polyamides such as nylon 6 and nylon 66; polyolefins such as polypropylene; polyimides, polyvinyl alcohol and their copolymers (col. 3, lines 5-11).

**Finding of prima facie obviousness
Rationale and Motivation (MPEP 2142-2143)**

It would have been obvious to one of ordinary skill in the art at the time of invention to combine the teachings of Kokubo et al. and Fujita et al. and use polyolefin, polyester and nylon as the base material. One of ordinary skill in the art at the time the invention was made would have been motivated to use polyolefin, polyester or nylon as the base material because Kokubo et al. teach that any organic polymer which has

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affinity to mammal such as human and can form a titania layer which has apatite forming ability in supersaturated aqueous solution with respect to the apatite can be used including polyolefin. The skilled artisan would have been motivated with a reasonable expectation of success to use polyolefin, polyester or nylon because Fujita et al. teach that these polymers are combined with tetraisopropyltitanate, the claimed titaniumtetraalkoxide, to form polymeric-shaped articles. Artificial bone is a shaped article.

In addition, the product produced by Kokubo et al., a titanium oxide-organic polymer composite material for artificial bone, is the same as the instantly claimed product. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)

Therefore, the claimed invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made because every element of the invention has been fairly suggested by the cited references.

Response to Arguments

Applicant's arguments filed November 17, 2009 have been fully considered but they are not persuasive. Applicant argues the specification teaches unexpected results when the claimed base materials are used to make the claimed composite material.

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Applicant claims the titanium oxide layer formed in the present invention is more suitable for artificial bone, because it has high bioactivity and high resistance to peeling, which is confirmed by the removing test. In response to Applicant's argument, the data provide is not convincing. It appears that according to Fig. 3, the apatite formation occurs between 30 and 35 2θ (CuK α)/ $^\circ$ for all of the polymers tested, PE, Nylon, and EVOH. Applicant provides no data to show the purported high bioactivity. Fig. 5 does appear to show that the EVOH treated surfaces were peeled, however, this is not enough evidence to show that the compositions are materially different.

Applicant also argues Kokubo et al. do not teach the polymer is selected from a group consisting of polyester and nylon and that the technical field of Fujita is different from that of the present invention. In response to applicant's argument that Fujita is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Fujita is concerned with preparing insulating films on polymeric articles and forming films on polymer bases. The apatite that is formed is a result of Applicant's invention that forms films and insulates on the polymer base. In addition, Applicant claims a composition. Fujita teaches the components of Applicant's invention, a polymer base consisting of polyester and nylon, a titania solution comprising a tetrafunctional titanium compound such as TiCl_4 , tetraethyltitanate, tetraisopropyltitanate, and forming a gel on the surface of the base material by dipping

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into the titania solution. The use of the composition to form an apatite is an intended use, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Kokubo et al. teach that any organic polymer which has affinity to mammal such as human and can form a titania layer which has apatite forming ability in supersaturated aqueous solution with respect to the apatite can be used. As such, the skilled artisan would be motivated to use polyester or nylon as these polymers are the base polymers used in Fujita using the same components as Applicant's invention. In addition, it is known in the art that nylon is an organic polymer which has affinity to mammal and can form a titania layer as evidenced by the teaches of JP 2002-248163, incorporated by reference as delineated above.

None of the claims are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andriae M. Holt whose telephone number is (571)272-9328. The examiner can normally be reached on 7:00 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richter Johann can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Andriae M. Holt
Patent Examiner
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/Johann R. Richter/
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